



Allergy Therapeutics

**Interim results
for the six months ending
31 December 2017**

Delivering on our strategy – three areas for growth

March 2018



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Introduction to Allergy Therapeutics

Dedicated to allergy treatment and prevention



Leading allergy immunotherapy company with a portfolio of marketed products and strong development pipeline

Provide treatments that have potential to cure disease, not just symptoms. Focus on moderate to severe patients

Approximately 500 employees

Headquartered and manufacturing base in Worthing, West Sussex

Market capitalisation of approximately £150m, AIM ticker LSE:AGY

Double digit compound annual growth achieved over the past 18 years

Robust revenue growth and successful M&A delivered. Three pillar strategy for growth: Europe, pipeline and US

Spun out of Smith Kline Beecham in 1999

Products currently in trials for the US market



Financial highlights

~ Double digit compound annual growth achieved over the past 18 years ~

1.3%* ▲

increase in revenue
at constant currency** to

£40.9m

(H1 2017: £40.4m)

4.4% ▲

increase in
revenue at

£42.2m

(H1 2017 £40.4m)

Solid growth in operating profit pre R&D up

12% to £12.3m

as a result of leveraging sales growth, a stated aim of management

(H1 2017: £11.1m)

R&D expenditure of

£5.9m

(H1 2017: £3.8m)

Cash balance of

£25.8m

(H1 2017: £27.8m)

*Percentage based on numbers in thousands (H1 2018: £40.956m, H1 2017: £40.427m)

** Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements. See table in financial review for an analysis of revenue.

N.B. All financial dates refer to the financial year. All clinical dates refer to the calendar year.

Operational highlights

Increased market share in Germany

14%

(2017: 13%)



Solid revenue growth across Europe – strong performance from Venomil and Acarovac Plus



Completion of recruitment for pivotal Phase III Pollinex Quattro Birch trial
Completion of recruitment for US Grass Mata MPL Phase II trial ahead of schedule



Contract for scale up of Polyvac peanut signed with aim for first trial in humans in 2019



Acarovac Phase I trial continues with read out expected in H1 2019



Contract for Oralvac joint development signed with Ergomed. TAV projects on track



Strategy

March 2018



Delivering our strategy

Three pillars to the business

Expanding in Europe



Strongly performing
profitable business

Growing market share
and additional product
registrations

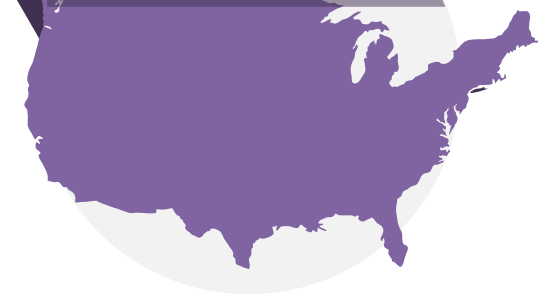
Strong pipeline



New technologies
underpin pipeline breadth and depth

Investment strategy
supported by growing
revenue stream

Preparing for US entry



Significant opportunity
in largest allergy market

Changing environment
to drive market share
towards Allergy's products



Delivering our strategy

EXPANDING IN EUROPE





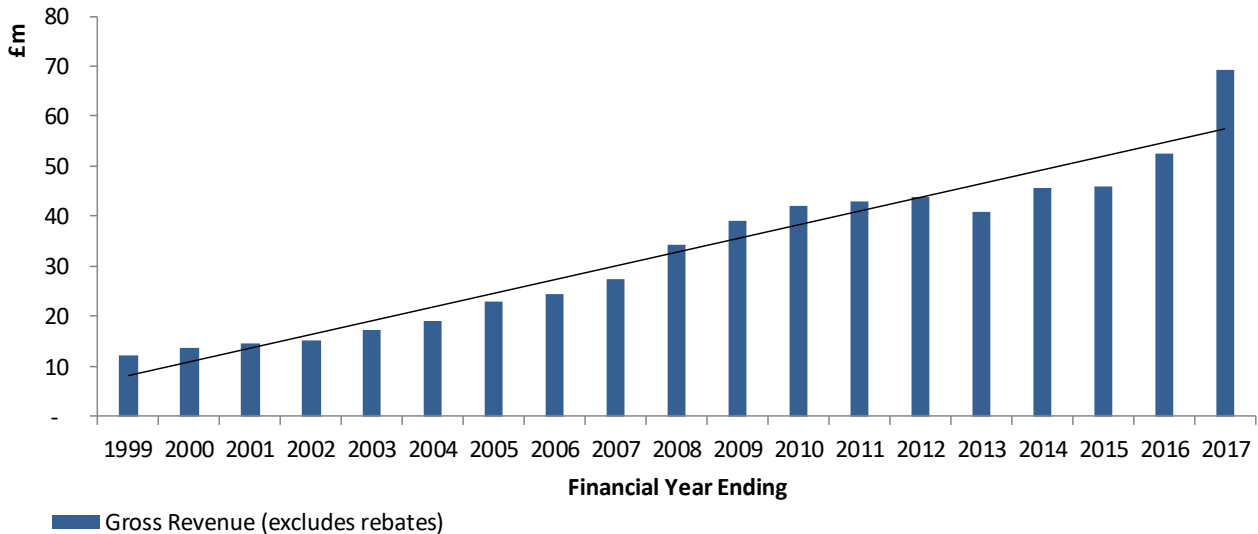
Delivery of European growth strategy



Solid sales growth of 1.3%* in H1 2018 and increased German market share to 14% from 13% driven by:

- Innovative, convenient and patient-friendly (short-course) products
- Increased regulatory requirements to ATL advantage (TAV)
- Focused investment across business reflected in performance
- Strength of broad portfolio with Acarovac Plus and Venomil
- Scaling-up to drive technological and geographical expansion

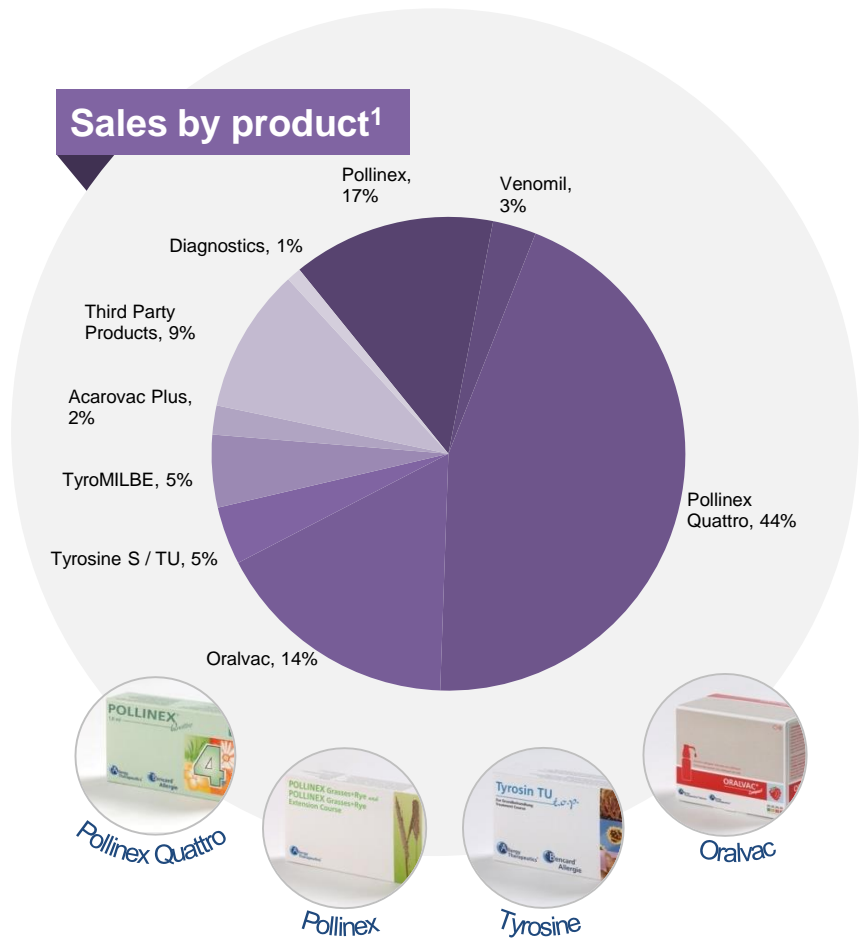
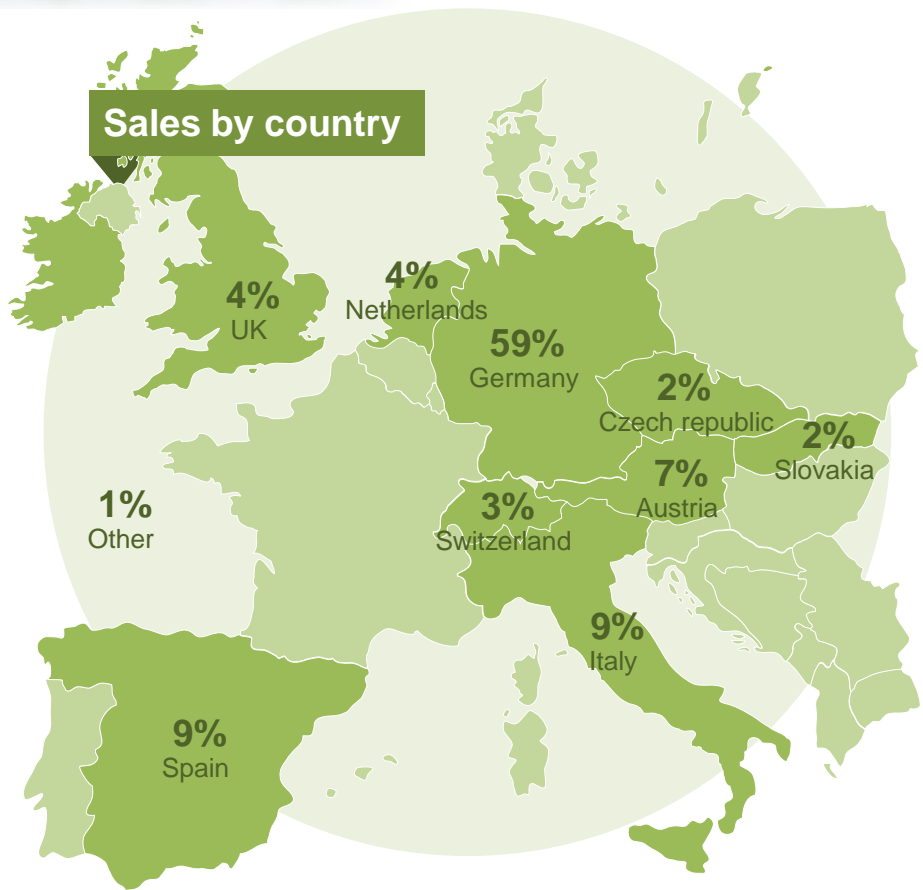
Double digit CAGR growth over the last 18 years since formation (full year data)



*Percentage based on figures in thousands (H1 2018: £40.956m, H1 2017: £40.427m)



Sales breakdown for FY 2017



1. Sales breakdown based on gross sales at budget exchange rates (before freight, discounts, rebates and exchange) : £63.2 million. After deducting discounts, rebates, freight charges and foreign exchange adjustments, total sales for FY2017 is £64.1 million



Delivering our strategy

STRONG PIPELINE





TAV (Therapy Allergy Ordinance) process



TAV German process initiated in 2008 and driven by the Paul Ehrlich Institute based on European legislation

Includes all products without registration

40% of all submitted products have now been removed from the process and are no longer on the market (PEI Seminar, 2017)

Germany contributes 59% of AGY Group sales

Future advantage of clinical evidence to support marketing plus potential reduction in competition

All of Allergy's products submitted in 2011 are still in process



Broad pipeline

	Pre-clinical	Phase I	Phase II	Phase III	Market/Registered	Also available as a Named Patient Product
Pollinex Grass			Short-course SCIT			
Pollinex Tree			Short-course SCIT			
Pollinex Ragweed			Short-course SCIT			
Venomil Bee			Bee venom SCIT			
Venomil Wasp			Wasp venom SCIT			
Pollinex Quattro Grass *		Short-course Grass SCIT with MPL				✓
Pollinex Quattro Birch		Short-course Birch SCIT with MPL				✓
Pollinex Quattro Ragweed		Short-course Ragweed SCIT with MPL				-
Pollinex Quattro Grass **		Short-course Grass SCIT with MPL				-
Pollinex Quattro Trees		Short-course Tree SCIT with MPL				✓
Oralvac Grass, Trees & house dust mite		Sublingual immunotherapy with flexible-dosing				✓
Acarovac Platform		Short-course modified Allergen HDM SCIT + MPL				✓
Polyvac Peanut		Short-course Peanut SCIT				

* - 0.5mL formulation
 ** - 1.0 mL formulation



Pipeline trials

Positive top-line results for Phase II Birch dosing study (B204) using conjunctival provocation test

PQ Birch – Phase III (Germany – TAV process)

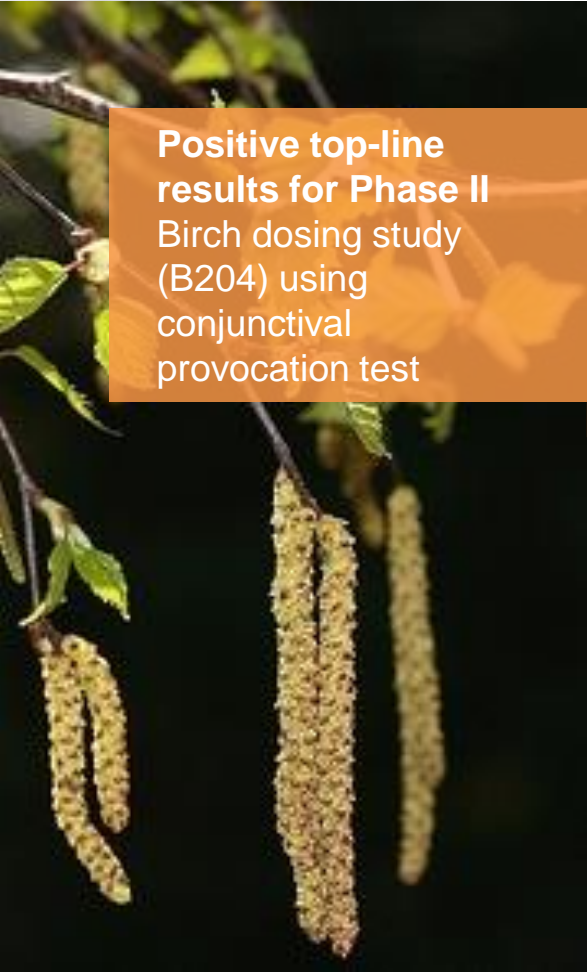
- Recruitment completed and patients already being treated
 - Results expected H2 2018
 - If successful, regulatory submission 2019
-

PQ Grass – Phase II (US & Germany TAV process)

- Recruitment completed early and patients already being treated
 - Results expected ahead of schedule in early H2 2018
 - If successful, second Phase III study to follow in US/Europe
-

Acarovac MPL Phase I

- Trial with 32 patients in progress in Spain
- Results expected H1 2019
- Potential for US market with two Phase III trials





Polyvac peanut product

Positive results achieved from preclinical research of Polyvac Peanut

Single dose of virus like particle (VLP) combined with recombinant peanut allergen successfully **protects against anaphylaxis** when challenged with peanut

Those vaccinated with candidate vaccine exhibited no symptoms compared to placebo, when challenged with peanut

Safety profile of product evaluated and found **not to induce anaphylaxis**

Manufacturing contract for scale-up of Polyvac product signed with Biomeva with aim of having first in human trial in 2019

Peanut represents a new opportunity into \$8bn* worldwide food allergy market

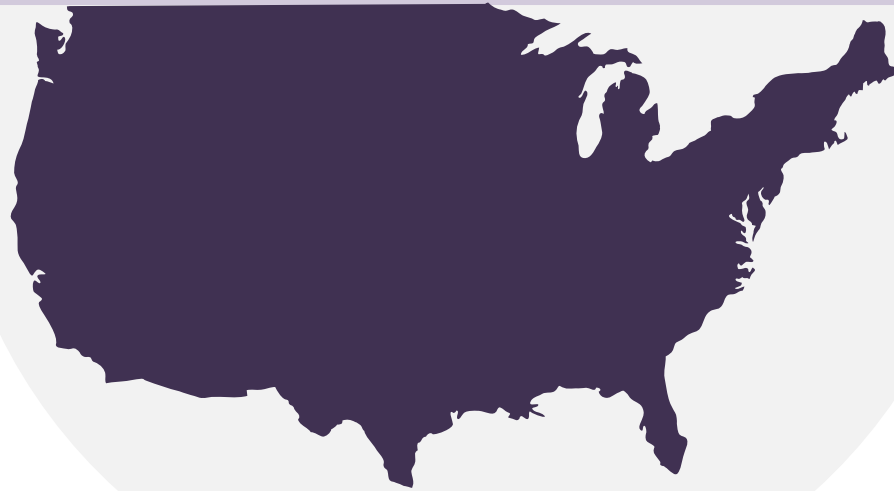
Pre-clinical development progressing according to plan with important product differentiation demonstrated – aim is long-term immunity

*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of \$2k



Delivering our strategy

PREPARING FOR US ENTRY





Portfolio of products to capture US opportunity



**Pollinex
Quattro
Grass**



**Pollinex
Quattro
Ragweed**



**Pollinex
Quattro
Trees**



Acarovac



**Polyvac
Peanut**

- ✓ **Proprietary, IP protected technology**

- ✓ **De-risked opportunity**
 - Treated more than 250,000 patients and marketed in 7 countries (pollens)

- ✓ **First mover advantage**
 - First to market in the seasonal injected segment
 - High entry barriers: regulatory requirements for extensive trials on efficacy and safety

- ✓ **Strategic fit for US market**

- ✓ **Building on progress to date in the US:**
 - \$100m invested in clinical studies to date
 - 15 clinical trials completed to date, including Phase I, II & III successful studies
 - Investigated in over 3,000 patients worldwide, mainly in the US



The evolving US opportunity



* Hankin CS, Cox L, Lang D, et al 2007 JACI

**Internal estimate

***Professor Lawrence DuBuske MD



Financial results

March 2018



P&L – six months ended 31 December 2017

	H1 2018 £'m	H1 2017 £'m	Variance £'m	%
Revenue	42.2	40.4	1.8	4%
Gross profit	33.5	31.5	2.0	6%
Overheads	(21.4)	(20.5)	(0.9)	(4%)
R&D	(5.9)	(3.8)	(2.1)	
Other Income	0.2		0.2	
Operating profit	6.4	7.2	(0.8)	
Net Financing costs	(0.0)	(0.0)	0.0	
Tax	(0.4)	(0.4)	(0.0)	
Profit after tax	6.0	6.8	(0.8)	

Solid sales performance
in abnormally weak pollen season

Sales drive gross profit growth

Overheads up
due to FX and investment

Significant R&D investment last year
in US Grass study and PQ Birch in Europe

Operating profit pre-R&D of £12.3m
(H1 2017: £11.1m) due to investment,
leveraging solid sales



Sales – six months ended 31 December 2017

	H1 2018 £'m	H1 2017 £'m	Variance £'m	%
Gross Revenue at Constant Exchange Rate	44.9	44.3	0.6	1%
Rebate at Constant Exchange Rate	(4.0)	(3.9)	(0.1)	(3%)
Net Revenue at Constant Exchange Rate	40.9	40.4	0.5	1%
Effect of Foreign Exchange	1.3		1.3	
Net Revenue	42.2	40.4	1.8	4%

* Constant exchange rate Euro/£

Current exchange rate Euro/£

1.16

1.13

1.16

Strong sales increases in Spain and Eastern Europe

Most markets
performing robustly

Strong growth in
Venomil and Acarovac Plus

FX impact much lower in this period
as smaller difference between rates



Balance sheet at 31 December 2017

	2018 £'m	2017 £'m	Var £'m
Non-current assets			
Property, plant and equipment	9.8	9.7	0.1
Intangible assets	5.1	5.4	(0.3)
Investments	4.9	4.3	0.6
	19.8	19.4	0.4
Current Assets			
Trade and other receivables	10.9	10.7	0.2
Inventories	8.4	7.0	1.4
Cash	25.8	27.8	(2.0)
Liabilities			
Financing liabilities	(3.2)	(3.4)	0.2
Other liabilities	(25.8)	(23.0)	(2.8)
Net assets	35.9	38.5	(2.6)
Equity			
Share capital and share premium	103.0	103.0	0.0
P&L account and other reserves	(67.1)	(64.5)	(2.6)
	35.9	38.5	(2.6)

Increase in non-current assets
driven by increase in pension
investments

Inventory higher
due to preparation for clinical trial
material

Cash position
of £25.8m

Debt of £3.2m
Seasonal overdraft in place (undrawn)

Other liabilities increase
due to R&D creditors



Cashflow for the six months ended 31 December 2017

	2018		2017	
	£'m	£'m	£'m	£'m
Opening cash balance 1st July		22.1		23.4
(Loss)/Profit before tax	6.4		7.2	
Adjustments re operations	<u>(2.1)</u>		<u>(1.7)</u>	
Net cash (used)/ generated by operations		4.3		5.5
Tax received/paid		0.7		0.0
Interest paid		(0.1)		(0.1)
Interest received	0.1		0.1	
Investments and acquisitions	(0.2)		(0.1)	
Capital expenditure	<u>(1.0)</u>		<u>(1.4)</u>	
Net cash used in investing activities		(1.1)		(1.4)
Proceeds from issue of shares	0.0		0.0	
Net movement in borrowings	<u>(0.1)</u>		<u>(0.1)</u>	
Net cash generated in financing activities		(0.1)		(0.1)
Effects of exchange rates on cash		0.0		0.5
Closing Cash Balance 31 December		25.8		27.8

Positive net cash generated by growth in business and foreign exchange benefit

Significant tax received due to R&D tax credit from 2017 financial year

Strong Cash position of £25.8m driven by solid performance and timing of R&D investment



Summary and outlook

March 2018



Summary and outlook

2018 set to be a pivotal year

Solid trading in H1 2018:

1.3*% 

sales growth at
constant currency

14%

market share Germany



Delivering against our strategy: three pillars to growth



Robust financials set to continue



Clinical trials progressing as planned – broad pipeline underpinned by innovative technologies



Focused strategy to be first to market in the US SCIT segment



2018 set to be a pivotal year:

- Growth and expansion in European business
- Results of pivotal Birch Phase III trial and US Grass Phase II trial
- Robust future product development pipeline



Board remains confident about Group's future prospects

*Percentage based on figures in thousands (H1 2018: £40.956m, H1 2017: £40.427m)



2018 expected key value driving newsflow



Full year results

Early H2 2018

PQ Grass Phase II for US and Europe – results of conjunctival provocation test dosing trial in Europe

H2 2018

PQ Birch Phase III for Europe
- results of pivotal field trial for PQ technology and part of the TAV process

H1 2019

Acarovac MPL Phase I – results for the new dust mite technology which could be developed for the Global market



Appendix

March 2018



Analysis of regulated products

	Named patient basis	Approved ¹	German TAV process	US Process	Other Clinical trials
Vaccines					
Pollinex	X	X			
Pollinex Quattro Grass	X		X	X	
Pollinex Quattro Birch	X		X		
Pollinex Quattro Ragweed	X			X	
Pollinex Quattro Trees	X		X	X	
Pollinex Quattro Grass & Birch	X		X		
Pollinex Quattro Grass & Tree	X		X		
Pollinex Quattro Grass & Mugwort	X		X		
<hr/>					
Acarovac Plus	X	X			
Acarovac MPL					X
<hr/>					
TyroMILBE	X		X		
Venomil	X	X			
TA Top	X				
Oral					
Oralvac Grass	X		X		
Oralvac Trees	X		X		
Oralvac House Mite	X		X		

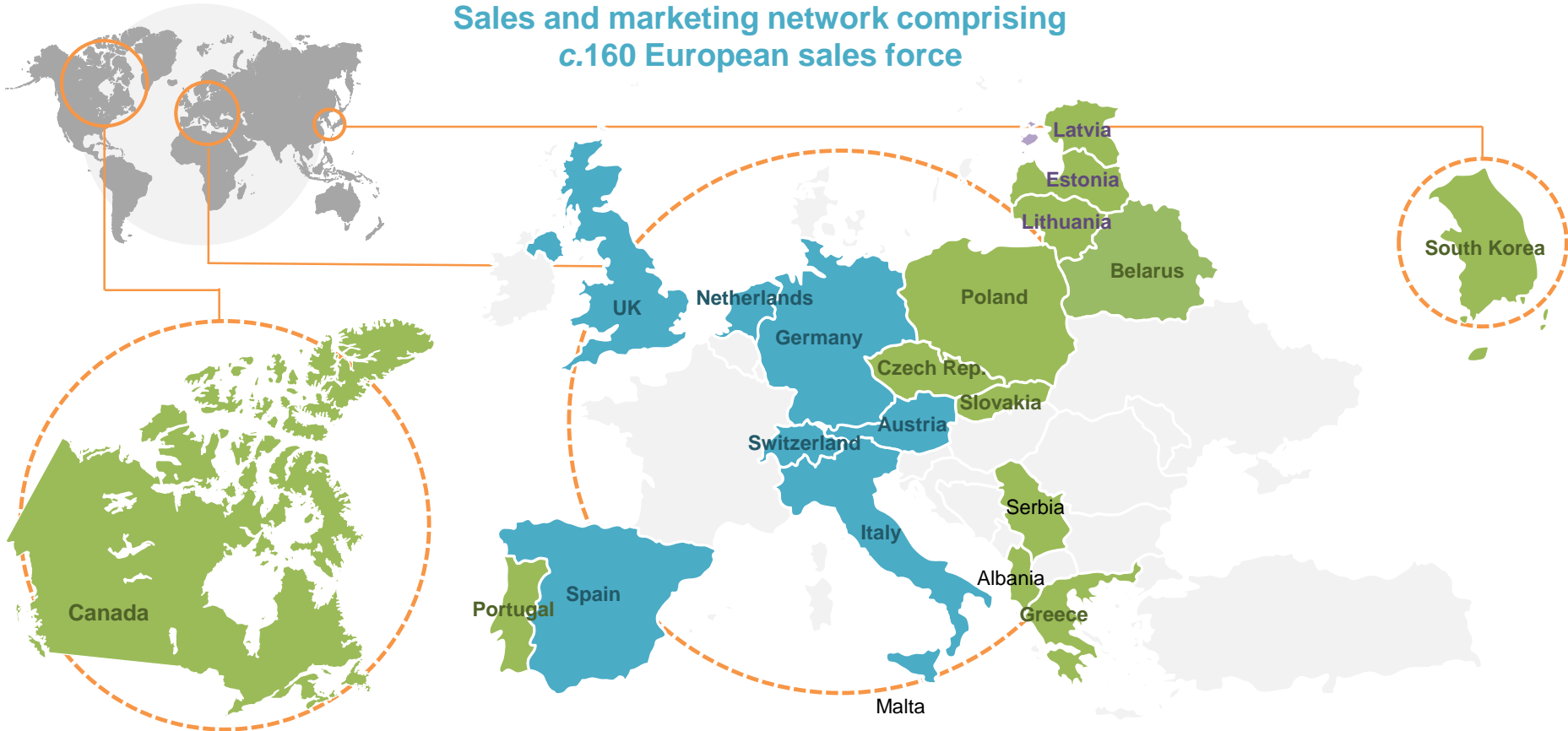
Trials in process
 CMC process
 Trials undertaken

¹ Approved in Germany or other major market



Global presence

Sales and marketing network comprising c.160 European sales force

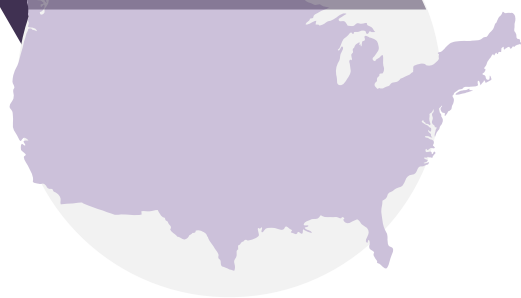


Subsidiaries in 7 countries and distribution agreements in additional 14 countries



Changing US landscape to drive market share

Current US SCIT market



Home made, unlicensed preparation

Non GMP manufacturing
Non registered
No clinical evidence

Long courses of treatment:
50 to 100 injections

Slow to act: 6 to 12 months

Low compliance

New USP and FDA regulations drive towards pharmaceutical grade, centrally manufactured, single allergen treatments

Allergy Therapeutics' entry in the US



Standardised dose vaccine

GMP manufactured
FDA submission
Multiple clinical studies

Ultra- short course treatment:
4 to 6 injections

Efficacy in 3 weeks

High compliance



Microcrystalline tyrosine (MCT)



Patent protection for MCT *Processing patent covers MCT*

MCT particles are formulated as sterile in state of the art processes enabling defined particle morphology and size optimised for binding to wide variety of antigens.

MCT Process patent extended-UK (2032)/EU filing 2032

R&D update Allergy / Non – Allergy indications

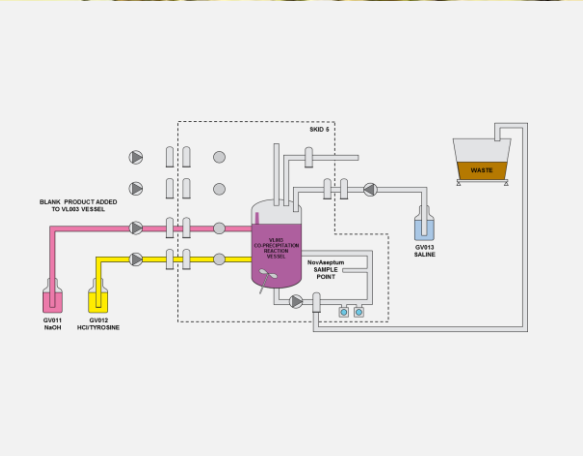
Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

Key publication in The Journal of Inorganic Biochemistry provides insight to the role of the (MCT) for use in existing and future therapeutic development incl. synergies with MCT and MPL in our Pollinex Quattro brand

Immunomodulation of MCT in allergy (publication pending 2016) – University of Zurich

MCT improves efficacy in non-allergy models (Influenza, Malaria) – Public Health England, University of Oxford (Jenner Institute), respectively. (publication in preparation)

MCT to enhance immunogenicity of different vaccines – for malaria study





PQ: a unique platform technology

Pollinex Quattro:
4 injections in 3 weeks, efficacy in 3 weeks

MPL Adjuvant

MPL Adjuvant

MPL (Monophosphoryl Lipid A) is a non-toxic derivative of lipopolysaccharide (LPS))

MPL allows the SIT treatment course to be shortened (big impact on adherence)

Regulates expression of co-stimulatory molecules on antigen-presenting cells

Acts locally as a TLR4 agonist and increases IgG production

Allergoid

Allergoid

Allergen chemically modified with glutaraldehyde

Retains IgG-allergen stimulating properties patient adherence

Reduces IgE reactivity vs. that induced by native allergens used in SIT

Micro Crystalline Tyrosine (MCT)

MCT

A natural amino acid which is readily metabolised

L Tyrosine retains the Allergoid and MPL at the site of injection (half life = 48 hours) as depot

30-year history of safe use in vaccines

Rebalances TH1 response



Acarovac MPL house dust mite product

Short-course product with global potential



Phase I first patient treated in June 2017 as part of 32 patient trial (AM101)

Acarovac product without MPL growing well in Spain and Austria

Potential of 8 injection model compared to 12-15 average of competitors and once a day for 3 years oral treatment

Results of Phase I Trial expected H1 2019

Market opportunity of \$3-4bn* worldwide with only Europe partly tapped already

Potential additional product in US portfolio following two Phase III trials

*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of \$2k



Bencard Adjuvant Systems division

Strategy

MCT, MPL & VLP
Researching on MCT
mechanism of action

Potential for licencing or
use in development of
products to boost efficiency

Studies

Pre-clinical study using MCT in a
seasonal influenza model – elicited
immune response indicative of protection

Pre-clinical model using MCT and
VLP in malaria – offered best
protection compared with antigens
formulated with aluminium

Studies show MCT both alone and in
adjuvant system elicit high, sustained
antibody titres demonstrating enhanced
protective efficacy compared to
conventional adjuvants including aluminium



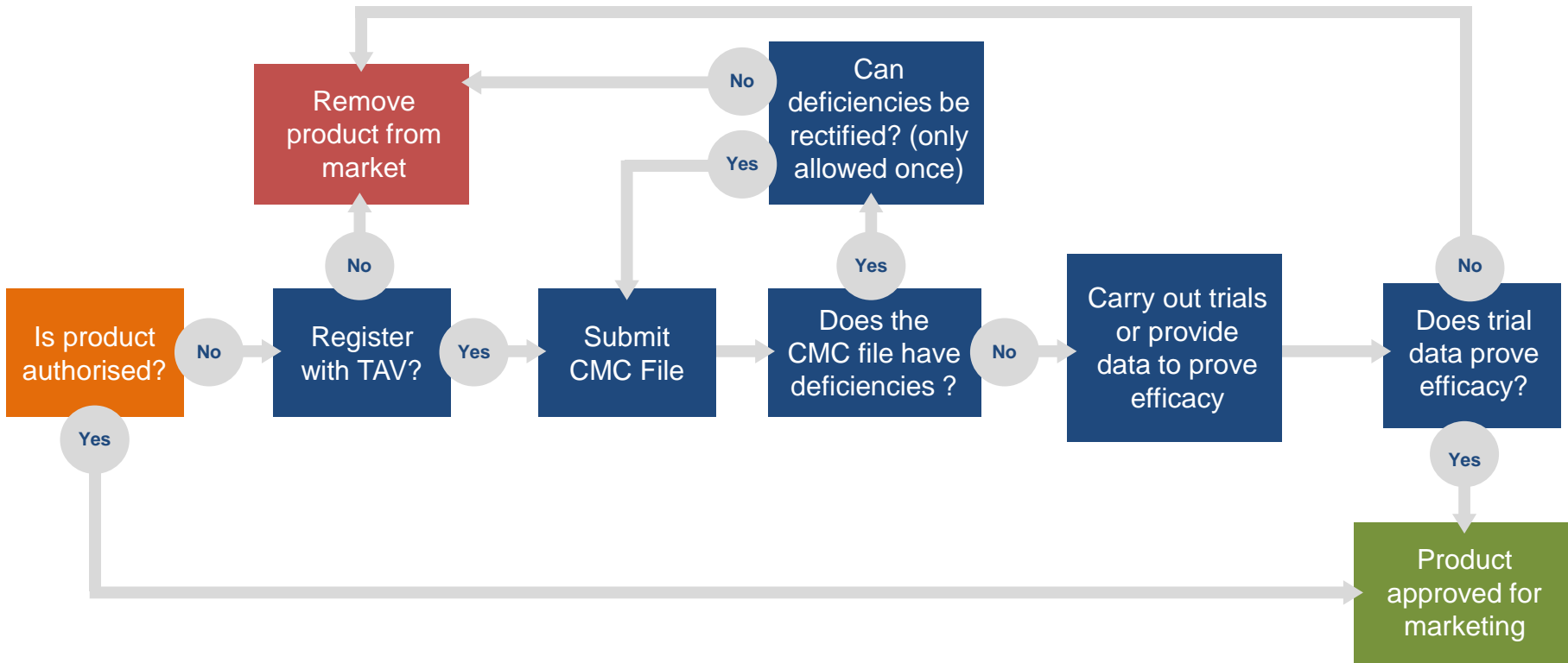
Platform technologies

	Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalline Tyrosine (MCT)	Monophosphoryl Lipid A (MPL)	Virus-Like Particles (VLP)
Pollinex	✓	-	-	✓	-	-
Pollinex Quattro	✓	-	-	✓	✓	-
Oralvac	-	✓	-	-	-	-
Acarovac Plus	✓	-	-	✓	-	-
Acarovac MPL	✓	-	-	✓	✓	-
Venomil	-	✓	-	-	-	-
Peanut*	-	-	✓	✓	-	✓

* - Product under pre-clinical investigation, full product profile yet to be determined



TAV process



Notes:

- 1. While in the TAV process all products can continue to be sold. Once rejected they must be removed from the market
- 2. All products must either have been approved or must go through the TAV process
- 3. The trials needed are tolerability, dose ranging and efficacy